

House Study Bill 226

SENATE/HOUSE FILE _____
BY (PROPOSED DEPARTMENT OF
PUBLIC HEALTH/BOARD OF
PHARMACY EXAMINERS BILL)

Passed Senate, Date _____ Passed House, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act providing for the creation of an electronic drug database,
2 establishing fees, providing penalties, and providing an
3 effective date.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:
5 TLSB 1293DP 81
6 rn/sh/8

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1 1 Section 1. Section 22.7, Code 2005, is amended by adding
1 2 the following new subsection:
1 3 NEW SUBSECTION. 51. The information contained in the
1 4 electronic drug database established in section 124.510A,
1 5 except to the extent that disclosure is authorized pursuant to
1 6 section 124.510C.
1 7 Sec. 2. NEW SECTION. 124.510A ELECTRONIC DRUG DATABASE
1 8 ESTABLISHED.
1 9 The board shall establish and maintain an electronic drug
1 10 database. The board shall use the electronic drug database to
1 11 monitor the misuse, abuse, and diversion of selected
1 12 controlled substances and other drugs the board includes in
1 13 the database pursuant to section 124.510E, subsection 1,
1 14 paragraph "i". The board shall electronically collect and
1 15 disseminate information pursuant to sections 124.510C and
1 16 124.510D and rules adopted pursuant to this division. The
1 17 board may contract with a third-party/private vendor to
1 18 administer the electronic drug database.
1 19 Sec. 3. NEW SECTION. 124.510B DATA REPORTING.
1 20 1. Each licensed pharmacy that dispenses selected drugs
1 21 identified by the board by rule to patients in the state, and
1 22 each licensed pharmacy located in the state that dispenses
1 23 such selected drugs to patients inside or outside the state,
1 24 unless specifically excepted in this section or by rule, shall
1 25 submit the following prescription information to the board or
1 26 its designee:
1 27 a. Pharmacy identification.
1 28 b. Patient identification.
1 29 c. Prescriber identification.
1 30 d. The date the prescription was issued by the prescriber.
1 31 e. The date the prescription was dispensed.
1 32 f. An indication of whether the prescription dispensed is
1 33 new or a refill.
1 34 g. Identification of the drug dispensed.
1 35 h. Quantity of the drug dispensed.
2 1 i. The number of days' supply of the drug dispensed.
2 2 j. Serial or prescription number assigned by the pharmacy.
2 3 k. Source of payment for the prescription.
2 4 2. Information shall be submitted electronically in the
2 5 format specified by the board unless the board has granted a
2 6 waiver and approved an alternate format.
2 7 3. Information shall be timely transmitted as designated
2 8 by the board by rule, unless the board grants an extension.
2 9 The board may grant an extension if either of the following
2 10 occurs:
2 11 a. The pharmacy suffers a mechanical or electronic
2 12 failure, or cannot meet the deadline established by the board
2 13 for other reasons beyond the pharmacy's control.
2 14 b. The board or its designee is unable to receive
2 15 electronic submissions.
2 16 4. This section shall not apply to a prescriber
2 17 furnishing, dispensing, supplying, or administering drugs to

2 18 the prescriber's patient, or to dispensing by a licensed
2 19 pharmacy for the purposes of inpatient hospital care,
2 20 inpatient hospice care, or long-term residential facility
2 21 patient care.

2 22 Sec. 4. NEW SECTION. 124.510C DATA ACCESS.

2 23 1. The board or its designee may provide information from
2 24 the electronic drug database to all of the following:

2 25 a. A person who is a designated representative of a
2 26 governmental entity responsible for the licensure, regulation,
2 27 or discipline of licensed health care professionals authorized
2 28 to prescribe or dispense drugs, who is involved in an
2 29 investigation of a person licensed, regulated, or subject to
2 30 discipline by the entity, and who is seeking access to
2 31 information in the database that is relevant to the subject
2 32 matter of the investigation and pursuant to a written probable
2 33 cause determination.

2 34 b. A federal, state, county, township, or municipal
2 35 officer of this or any other state, or the United States,
3 1 whose duty it is to enforce the laws relating to prescription
3 2 drugs and who is actively engaged in a specific investigation
3 3 of a specific person and is seeking access to information in
3 4 the database pursuant to a probable cause determination or
3 5 warrant.

3 6 c. A properly convened grand jury pursuant to a subpoena
3 7 properly issued.

3 8 d. A pharmacist or prescriber who requests the information
3 9 and certifies in a form specified by the board that it is for
3 10 the purpose of providing medical or pharmaceutical care to a
3 11 patient of the pharmacist or prescriber.

3 12 e. An individual who requests the individual's own
3 13 database information in accordance with the procedure
3 14 established in rules of the board adopted under section
3 15 124.510E.

3 16 2. The board or its designee shall maintain a record of
3 17 each person that requests information from the database.
3 18 Pursuant to rules adopted by the board under section 124.510E,
3 19 the board may use the records to document and report
3 20 statistics and law enforcement outcomes and to identify
3 21 inappropriate access or other prohibited acts. The board or
3 22 its designee may provide records of a person's requests for
3 23 database information to the following persons:

3 24 a. Pursuant to a probable cause determination, a
3 25 designated representative of a governmental entity that is
3 26 responsible for the licensure, regulation, or discipline of
3 27 licensed health care professionals authorized to prescribe or
3 28 dispense drugs who is involved in a specific investigation of
3 29 the individual who submitted the request.

3 30 b. Pursuant to a probable cause determination or warrant,
3 31 a federal, state, county, township, or municipal officer of
3 32 this or any other state or the United States, whose duty is to
3 33 enforce the laws relating to prescription drugs, and who is
3 34 actively engaged in a specific investigation of the specific
3 35 person who submitted the request.

4 1 3. Information contained in the database and any
4 2 information obtained from it is strictly confidential medical
4 3 information, is not a public record pursuant to chapter 22,
4 4 and is not subject to discovery, subpoena, or other means of
4 5 legal compulsion for release except as provided in this
4 6 division. Information contained in the records of requests
4 7 for information from the database is privileged and
4 8 confidential, is not a public record, and is not subject to
4 9 discovery, subpoena, or other means of legal compulsion for
4 10 release except as provided in this division. Information from
4 11 the database shall not be released, shared with an agency or
4 12 institution, or made public except as provided in this
4 13 division.

4 14 4. Information collected for the database shall be
4 15 retained in the database for four years. The information
4 16 shall then be destroyed unless a law enforcement agency or a
4 17 governmental entity responsible for the licensure, regulation,
4 18 or discipline of licensed health care professionals authorized
4 19 to prescribe or dispense drugs has submitted a written request
4 20 to the board or its designee for retention of specific
4 21 information in accordance with rules adopted by the board
4 22 under section 124.510E.

4 23 5. A pharmacist or other dispenser making a report to the
4 24 database in good faith pursuant to this division is immune
4 25 from any liability, civil, criminal, or administrative, which
4 26 might otherwise be incurred or imposed as a result of the
4 27 report.

4 28 6. Nothing in this section shall require a pharmacist or

4 29 prescriber to obtain information about a patient from the
4 30 database. A pharmacist or prescriber does not have a duty and
4 31 shall not be held liable in damages to any person in any civil
4 32 or derivative criminal or administrative action for injury,
4 33 death, or loss to person or property on the basis that the
4 34 pharmacist or prescriber did or did not seek or obtain
4 35 information from the database. A pharmacist or prescriber
5 1 acting in good faith is immune from any civil, criminal, or
5 2 administrative liability that might otherwise be incurred or
5 3 imposed for requesting or receiving information from the
5 4 database.

5 5 7. The board shall not charge a fee to a pharmacy,
5 6 pharmacist, or prescriber for the establishment, maintenance,
5 7 or administration of the database. The board shall not charge
5 8 a fee for the transmission of data to the database nor for the
5 9 receipt of information from the database, except that the
5 10 board may charge a reasonable fee to an individual who
5 11 requests the individual's own database information or to a
5 12 person requesting statistical, aggregate, or nonpersonally
5 13 identified information from the database. A fee charged
5 14 pursuant to this subsection shall not exceed the cost of
5 15 providing the requested information and shall be considered a
5 16 repayment receipt as defined in section 8.2.

5 17 Sec. 5. NEW SECTION. 124.510D DATA REVIEW AND REFERRAL.

5 18 The board or its designee shall review the information in
5 19 the electronic drug database. If the board determines,
5 20 consistent with the board's authority under this chapter or
5 21 chapter 155A, that there is probable cause to believe that
5 22 drug diversion or another violation of law may have occurred,
5 23 the board shall notify the appropriate law enforcement agency
5 24 or the governmental entity responsible for the licensure,
5 25 regulation, or discipline of the licensed health care
5 26 professional, and shall supply information required to
5 27 initiate an investigation. The board shall not refer
5 28 information relating to an individual for further
5 29 investigation except upon a probable cause determination. A
5 30 probable cause determination shall be consistent with
5 31 guidelines developed by the advisory council established under
5 32 section 124.510F.

5 33 Sec. 6. NEW SECTION. 124.510E RULES AND REPORTING.

5 34 1. The board shall adopt rules in accordance with chapter
5 35 17A to carry out the purposes of, and to enforce the
6 1 provisions of, this division. The rules shall include but not
6 2 be limited to the development of procedures relating to:

6 3 a. Identifying each patient about whom information is
6 4 entered into the electronic drug database.

6 5 b. An electronic format for the submission of information
6 6 from pharmacies.

6 7 c. A waiver to submit information in another format for a
6 8 pharmacy unable to submit information electronically.

6 9 d. Granting by the board of a request from a law
6 10 enforcement agency or a governmental entity responsible for
6 11 the licensure, regulation, or discipline of licensed health
6 12 care professionals authorized to prescribe or dispense drugs
6 13 for the retention of information scheduled for deletion from
6 14 the database after four years when the information pertains to
6 15 an open investigation being conducted by the agency or entity.

6 16 e. An application for an extension of time by a pharmacy
6 17 regarding information to be transmitted to the board or its
6 18 designee.

6 19 f. The submission by a person or governmental entity to
6 20 which the board is authorized to provide information of a
6 21 request for the information and a procedure for the
6 22 verification of the identity of the requestor.

6 23 g. Use by the board of the database request records
6 24 required by section 124.510C, subsection 2, to document and
6 25 report statistics and law enforcement outcomes and to identify
6 26 inappropriate access or other prohibited acts.

6 27 h. Submission of a request by an individual for the
6 28 individual's own database information and verification of the
6 29 identity of the requestor.

6 30 i. The development of a list of controlled substances and
6 31 other drugs that shall be included in the database.

6 32 j. Access by a pharmacist or prescriber to information in
6 33 the database pursuant to a written agreement with the board.

6 34 k. Terms and conditions of the contract, if the board
6 35 contracts for database administration with a third-party or
7 1 private vendor.

7 2 l. The correction or deletion of erroneous information
7 3 from the database.

7 4 2. No later than January 1, 2008, and every two years

7 5 thereafter, the board shall present to the general assembly
7 6 and the governor a report of the following:
7 7 a. The cost to the state of implementing and maintaining
7 8 the database.
7 9 b. Information from pharmacies, prescribers, the board,
7 10 and others regarding the usefulness of the database.
7 11 c. Information from pharmacies, prescribers, the board,
7 12 and others regarding the board's effectiveness in providing
7 13 information from the database.
7 14 d. Information documenting the timely transmission of
7 15 information from the electronic drug database to authorized
7 16 requestors.

7 17 Sec. 7. NEW SECTION. 124.510F ADVISORY COUNCIL
7 18 ESTABLISHED.

7 19 The board shall establish an advisory council to provide
7 20 oversight to the electronic drug database program. The board
7 21 shall adopt rules specifying the duties and activities of the
7 22 advisory council and related matters.

7 23 1. The council shall consist of three licensed
7 24 pharmacists, three licensed physicians, two licensed
7 25 prescribers who are not physicians, and two members of the
7 26 general public. The board shall solicit recommendations for
7 27 health professional council members from Iowa health
7 28 professional licensing boards, associations, and societies.
7 29 The license of each health professional appointed to and
7 30 serving on the advisory council shall be current and in good
7 31 standing with the professional's licensing board.

7 32 2. The council may make recommendations to advance the
7 33 goals of the database, which include identification of misuse
7 34 and diversion of identified controlled substances and other
7 35 drugs and enhancement of the quality of health care delivery
8 1 in this state.

8 2 3. Among other things, the council shall:

8 3 a. Assist the board in developing criteria for granting
8 4 requests by researchers and other persons for statistical,
8 5 aggregate, or nonpersonally identified information using
8 6 database information, developed consistent with the goals of
8 7 the database.

8 8 b. Assist the board in ensuring patient confidentiality
8 9 and the integrity of the patient's treatment relationship with
8 10 the patient's health care provider.

8 11 c. Make recommendations regarding the continued benefits
8 12 of maintaining the electronic drug database in relationship to
8 13 cost and other burdens to the board. The council's
8 14 recommendations shall be included in reports required by
8 15 section 124.510E, subsection 2.

8 16 3. Members of the advisory council shall be eligible to
8 17 request and receive actual expenses for their duties as
8 18 members of the advisory council, subject to reimbursement
8 19 limits imposed by the department of administrative services,
8 20 and shall also be eligible to receive a per diem compensation
8 21 as provided in section 7E.6, subsection 1.

8 22 Sec. 8. NEW SECTION. 124.510G PROHIBITED ACTS AND
8 23 PENALTIES.

8 24 The failure of a licensed pharmacist or licensed prescriber
8 25 to comply with the requirements of this division, or the
8 26 performance or causing the performance of, or the aiding and
8 27 abetting of another person in the performance of, any of the
8 28 prohibited acts identified in this section shall constitute
8 29 grounds for disciplinary action against the pharmacist or
8 30 prescriber by the appropriate professional licensing board.
8 31 Each licensing board that licenses prescribers and drug
8 32 dispensers subject to the provisions of this division may
8 33 adopt rules in accordance with chapter 17A to implement the
8 34 provisions of this section and may impose penalty as allowed
8 35 under section 272C.3. In addition, a civil penalty not to
9 1 exceed twenty-five thousand dollars for each violation may be
9 2 imposed.

9 3 1. A pharmacist who willfully and knowingly fails to
9 4 submit prescription information to the board or its designee
9 5 as required by this division, or who knowingly and
9 6 intentionally submits prescription information known to the
9 7 pharmacist to be false or fraudulent, may be subject to
9 8 disciplinary action by the board.

9 9 2. A person authorized to access or receive prescription
9 10 information pursuant to this division who willfully and
9 11 knowingly discloses or attempts to disclose such information
9 12 with the intent to cause harm to another person in violation
9 13 of this division is guilty of a class "D" felony.

9 14 3. A person who willfully and knowingly uses, releases,
9 15 publishes, or otherwise makes available to another person any

9 16 personally identifiable information obtained from or contained
9 17 in the database is guilty of a serious misdemeanor.

9 18 4. A person without lawful authority who obtains or
9 19 attempts to obtain information, obtains or attempts to obtain
9 20 unauthorized access to, or who willfully and knowingly alters
9 21 or destroys valid information contained in the database is
9 22 guilty of a class "D" felony.

9 23 5. A person authorized to access or receive prescription
9 24 information pursuant to this division who knowingly and
9 25 intentionally discloses confidential information to a person
9 26 who is not authorized to receive the information pursuant to
9 27 this division is guilty of a serious misdemeanor.

9 28 Sec. 9. EFFECTIVE DATE. This Act, being deemed of
9 29 immediate importance, takes effect upon enactment.

9 30 EXPLANATION

9 31 This bill authorizes the board of pharmacy examiners to
9 32 establish and administer a prescription drug database
9 33 containing a record of the dispensing of prescriptions for
9 34 identified controlled substances and prescription drugs. The
9 35 bill provides that the goals of the database program include
10 1 identification of misuse and diversion of prescription drugs
10 2 and enhancement of the quality of health care delivery in
10 3 Iowa.

10 4 The bill identifies minimum data requirements to be
10 5 reported by pharmacies dispensing to patients in Iowa, and for
10 6 pharmacies located in Iowa and dispensing to patients outside
10 7 the state, for the format and timeliness of data submissions,
10 8 for the exemption of specified entities from data submission
10 9 requirements, and for the adoption of rules by the board
10 10 regarding implementation of the database program.

10 11 The bill provides for the identification of persons
10 12 authorized to request information from the database program,
10 13 places limitations on access by certain authorized persons,
10 14 and requires that a record be made and maintained of any
10 15 request for database information. The bill provides that
10 16 information contained in the database or derived from the
10 17 database is confidential information, and provides protection
10 18 from liability for pharmacists and prescribers whether or not
10 19 they choose to utilize information from the database in the
10 20 medical treatment of patients.

10 21 The bill provides for the establishment of an advisory
10 22 council to provide oversight to the database program and
10 23 provides for the payment of per diem and council member
10 24 expenses. The bill additionally identifies actions and
10 25 information uses which are prohibited under the program and
10 26 the establishment of criminal, administrative, and civil
10 27 penalties for prohibited acts.

10 28 The bill provides for the addition of information contained
10 29 in the database to the list of confidential records in Code
10 30 section 22.7.

10 31 The bill takes effect upon enactment.

10 32 LSB 1293DP 81

10 33 rn:nh/sh/8.1